Exhibit L

Summary of Safety and Effectiveness

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

A. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Phone: 480-303-2539

Fax: 480-449-2546

Contact: Shari L. Allen, Director of Regulatory Affairs and Clinical Research

B. Subject Device Name: G2 Filter System

Common or Usual Name: Vena Cava Filter

Classification: Class II with Special Controls

The special controls for this device are compliant with the following:

- FDA's "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions", issued on November 26, 1999.
- BS EN 12006-3:1999 entitled, "Non-Active Surgical Implants - Particular Requirements for Cardiac and Vascular Implants - Part 3: Endovascular Devices".

C. Predicate Device

Device Name(s): Recovery Filter System (K022236, cleared 11/27/02)

Classification: Class II with Special Controls

D. **Subject Device Description:**

The G2 Filter System (subject) description is identical to the Recovery Filter System (predicate) description and indications for use. The modifications made to the predicate filter device and delivery system are primarily dimensional. No material changes or additional components have been incorporated.

The predicate filter device has been modified as a result of continued product improvement. The predicate delivery system has been modified to accommodate the geometry modifications of the predicate filter.

E. **Statement of Intended Use for Subject Device:**

The G2 Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

F. Substantial Equivalence:

The subject device has the following similarities to the predicate device that received clearance to market via K022236 on 11/27/02 and K031328 on 07/25/03:

- Same intended use;
- Same filter and delivery system materials;
- Same operating principle;
- Same fundamental scientific technology;
- Same packaging configuration and materials;
- Same sterility assurance level and method of sterilization.

The design, material, components, fundamental technology and intended use featured with the G2 Filter System are substantially equivalent to those featured with the predicate Recovery Filter System based on the design verification and validation activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2005

Bard Peripheral Vascular, Inc.
Shari Allen
Director of Regulatory Affairs and Clinical Research
P.O. Box 1740
Tempe, AZ 85280

Re: K050558
Trade Name: G2 Filter System
Regulation Number: 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II
Product Code: DTK
Dated: August 10, 2005
Received: August 11, 2005

Dear Ms. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Furthermore, the indication for permanent placement of the G2 Filter System must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

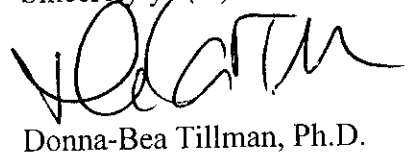
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050558

Indications For Use Statement

Device Name: G2 Filter System

Indications for Use: The G2 Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)0

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)